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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,215	02/19/2004	James A. McClain	030900	5338
41835	7590	12/05/2006	EXAMINER KRISHNAN, GANAPATHY	
KIRKPATRICK & LOCKHART NICHOLSON GRAHAM LLP HENRY W. OLIVER BUILDING 535 SMITHFIELD STREET PITTSBURGH, PA 15222			ART UNIT 1623	PAPER NUMBER

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,215	MCCLAIN, JAMES A.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 13 September 2006.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,3,4,6,7,9,10,12-16,18-24,26 and 27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,3,4,6,7,9,10,12-16,18-24,26 and 27 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>7/10/2006</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____.

DETAILED ACTION

The amendment filed 9/13/2006 has been received, entered and carefully considered.

The following information provided in the amendment affects the instant application:

1. Claims 2, 5, 8, 11, 17 and 25 have been canceled.
2. Claims 1, 15-16, 24 and 26-27 have been amended.
3. Remarks drawn to rejections under double patenting, 35 USC 112, second paragraph and 103.

Claims 1, 3-4, 6-7, 9-10, 12-16, 18-24 and 26-27 are pending in the case.

Claim Objections

Claim 27 is objected to because of the following informalities: Claim 27 is a duplicate of claim 24. Claim 27 should be cancelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-10, 12, 18-20 and 26 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making resistant starch, does not reasonably provide enablement for making resistant starch with the claimed whiteness level using the conditions as instantly claimed. The specification does not enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

- (A) The breadth of the claims
- (B) The level of one of ordinary skill
- (C) The amount of direction provided by the inventor
- (D) The existence of working examples
- (E) The level of predictability in the art
- (F) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

The recitation in the instant claims namely, the reaction temperature being between about 160 and about 175⁰C and the whiteness level is between about 65 to about 100 are fairly broad ranges.

The level of one of ordinary skill in the art

The level of skill of those in this art is that of one having experience in organic synthesis.

The amount of direction provided by the inventor

The specification (page 8) recites that the heating is done at temperatures between 140 and 180⁰C. This means that any temperature in the said range can be used to produce the starch with the whiteness level in the range 60-100.

The existence of working examples

The working examples set forth in the instant specification are drawn to heating of acidified corn starch to 140, 150 and 170°C until a whiteness level of 65 is reached. It is not clear if any other level of whiteness can be attained if different temperatures are used. A correlation between whiteness and temperature is not seen.

The level of Predictability in the Art

Ohkuma et al (US 5,358,729; used in the rejection below) teaches that there is an inverse relationship between whiteness and temperature (col. 23, Table 13). The process of Ohkuma is same as used instantly with the pH seen to be very close to the range as claimed in the instant process. In the example of Ohkuma heating at 170°C produces starch with a whiteness level of 21.2. Based on the results disclosed by Ohkuma one of ordinary skill in the art would not conclude that heating acidified starch to different temperatures as instantly claimed will produce a whiteness level of 65. According to Ohkuma the same level of whiteness cannot be obtained by heating the acidified starch to three different temperatures.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure

Indeed, in view of the information set forth, the instant disclosure is not seen to be sufficient to represent the process as instantly claimed for making resistant starch with the level of whiteness at temperatures as instantly claimed. One of ordinary skill in the art would have to carry out undue experimentation to practice the instant invention. One of ordinary skill in the art would be required to perform undue experimentation to determine the correlation of whiteness, temperature and pH.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-4, 6-7, 9-10, 12-16 and 19-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been overcome by amendment.

Double Patenting

Claims 1, 3-4, 6-7, 9, 12-16, 18, 20-24 and 26-27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 12-15, 18-23, 26-31 and 33-34 of copending Application No. 10/959,792 ('792 application) has been overcome by filing a Terminal Disclaimer, which has been approved.

The following new art rejection is made of record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6-7, 13-16, 21, 23-24 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohkuma et al (US 5,358,729) of record.

Ohkuma teaches the treatment of corn starch (limitation of claim 21) with hydrochloric acid solution, reducing the moisture content to about 8% (limitation of claims 13-14) and heating it to a temperature of 130, 140, 150, 150 and 170°C to obtain dextrin in about 80% yield (col. 14,

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lines 30-52; limitations of claims 15-16). The whiteness level of the product obtained at 140°C is about 51 (col. 23, Table 13). The pH is seen to be about 1 to about 4. This teaching is also seen to meet the limitations of instant claims 1, 3, 6-7, 24 and 27. Ohkuma teaches making of food products using the starch of his invention (see examples in Col. 35 through 54; limitation of claim 23).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohkuma et al (US 5,358,729) of record.

Ohkuma teaches the treatment of corn starch with hydrochloric acid solution, reducing the moisture content to about 8% and heating it to a temperature of 130, 140, 150, 150 and 170°C to obtain dextrin in about 80% yield. The whiteness level of the product obtained at 140°C is about 51 (col. 23, Table 13). The pH is seen to be about 1 to about 4. Ohkuma teaches that starch

other than corn starch like potato or tapioca starch can also be used for making resistant starch (col. 28, lines 55-65)). However, he does not teach the use gaseous hydrochloric acid or starch derived from rice, cassava or wheat.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use starch derived from other sources or gaseous hydrochloric acid in the process as instantly claimed since use of structurally close material and hydrochloric acid is taught in the prior art.

One of ordinary skill in the art would be motivated to use starch from other sources and gaseous HCl in order to extend the process to other types of starches that are structurally similar. This would yield resistant starch of different types. Gaseous HCl is also easier to manipulate compared to aqueous solutions.

Conclusion

Claims 1, 3-4, 6-7, 9-10, 12-16, 18-24 and 26-27 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK



Shaojia Jiang
Supervisory Patent Examiner
Art Unit 1623